DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date\Time: March 9, 2007

CBER Representatives: Celia Witten, Peter Bross, Ke Liu, Bo Zhen, Stephanie Simek, Raj Puri, Keith Wonnacott, Kimberly Benton Kathryn O'Connell, Malcolm Moos, Thomas Finn,Husain, Syed Husain, Miles Braun

Sponsor's Representative: Elizabeth Smith, Mark Frohlich, Lianng Yuh, Connie Spooner, Nicole Provost, David Urdal, Matt Harmon

STN : 125197/0

Subject: Weekly update telecon

Discussion:

Mortality Data:

- Complete ascertainment of mortality status at 3 years for 9901 and complete in all but 2 subjects in 9902A
- Minorities underrepresented in studies-
    - Dendreon is talking to investigators regarding how to address in ongoing study and for design of pharmacovigilance studies

Supportive Information:

- Time to Progression - data corrections after unblinding, baseline characteristics- CBER stated we used unblinded data sets with p value 0.085
- CD54-FDA explained that the interpretation of CD54 is limited by not having information on upregulation of processed cells from controls, and that the possibility of CD54 upregulation being a marker of patient could not be ruled out, although the sponsor had investigated to see if there were a correlation with known prognostic factors.

- Dendreon stated they would submit to BLA by 3/13/07the requested data on CD54 upregulation in the placebo and salvage groups

- Immunology data - would like Dendreon to discuss this data and what has been learned to date, their plans for collecting additional information and what could or could not be gained.

  - Dendreon stated these data were generated from 9901 and required fresh blood samples, so not obtained from all subjects. 9902B has been amended to collect and freeze samples from all subjects to comparative analysis in ELISPOT and other more current assays. 9902B data will not be available for several years.

  - CBER asked if Dendreson analyzed whether T cell stimulation index correlated with CD54 upregulation. Dendreon responsed there was no correlation.

Pharmacovigilance Plan

Dendreon will submit a draft and set up tcon with OBE

Additional items:

- CBER asked for clarification of figures in Dendreons' briefing document that did not appear to be in BLA. CBER clarified that the BD and presentations at the AC should not include any data not included in the BLA. Dendreon stated a flow cytometry figure in the BD used different gating than the BLA. CBER stated that is a concern because without access to raw data, CBER cannot do similar regating analyses.

- Dendreon asked if they could have "back-up" slides prepared to explain any questions at the AC meeting. CBER stated that no new data or analyses which had not been included in BLA should be presented at AC. CBER would inform the committee if any new material were presented

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